Comparison of surgical bypass with angioplasty and stenting of superficial femoral artery disease

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Objective: **To evaluate the contemporary outcome of femoral-popliteal bypass compared with angioplasty and stenting in patients with symptomatic peripheral arterial disease (PAD) in terms of patency and reintervention rates.**
Methods: **We identified all patients evaluated at the Johns Hopkins Bayview Medical Center with the presumptive diagnosis of PAD from September 2005 to September 2010. In this group, we selected all symptomatic patients after failing medical management who received percutaneous transluminal angioplasty/stenting of the superficial femoral artery or femoral-popliteal bypass. We compared the overall patency and reintervention rates between the two groups as well as patency within TransAtlantic Inter-Society Consensus (TASC) II subgroups. Descriptive analyses were performed using χ^2 and two-sided *t*-tests. The Mann-Whitney *U* test was used to compare distributions of continuous variables and the Fisher exact test for categorical variables. Cox proportional hazard model was used to examine the treatment effect within each lesion type, using bypass as the reference group.**
Results: **Out of 1237 patients evaluated at Johns Hopkins Bayview Medical Center for PAD from September 2005 to September 2010, we identified 104 symptomatic patients who received percutaneous transluminal angioplasty/stenting of the superficial femoral artery or femoral-popliteal bypass after failing medical management. There were 61 male patients (56%), and the mean age was 68 years in both groups. Both treatment groups had similar risk factors. Overall, 77% of patients with TASC II A and B lesions underwent angioplasty and stenting, whereas 73% of patients with TASC C and D lesions underwent bypass ($P < .01$). The primary patency at 24 months was better for the stent group 67% (95% confidence interval [CI], 0.52-0.78) vs bypass group 49% (95% CI, 0.32-0.64; $P = .05$). The rate of reintervention within the 2-year period was higher in the bypass group compared with the stent group (54% vs 31%; $P = .02$). TASC A and B lesions combined demonstrated a reduced hazard of patency failure compared with TASC C or D lesions combined (hazard ratio, 2.42; 95% CI, 1.26, 4.65; $P < .01$).**
Conclusions: **This is the first study that documents higher reintervention rates for femoral-popliteal bypass compared with angioplasty and stenting. We believe that the main reason for this finding is the fact that the bypass patients had significantly more advanced disease. This, emphasizes that one must consider the patient population undergoing intervention when comparing revascularization procedures. A prospective randomized trial is needed to determine the overall better treatment option. (J Vasc Surg 2014;59:129-35.)**

Surgical bypass using autogenous vein or prosthetic conduits, with the former being superior in patency, has been established as the gold standard revascularization method for the occluded superficial femoral artery (SFA) in intermittent claudication patients who failed medical management or in patients presenting with critical limb ischemia.[1-3] The 5-year primary patency rate of femoral-popliteal above the knee bypass with autogenous saphenous vein is 70%, while the primary-assisted patency can be improved to approximately 80%.[1] However, this method of treatment is invasive, with long incisions in the lower extremities and requires general or regional anesthesia. There is significant morbidity (10%-20%) and low but potential mortality (1%-2%) associated with the surgical approach.[4,5] As vascular surgeons became more experienced with catheter-based procedures in other vascular beds, they have adapted the minimally invasive percutaneous approach for lower extremity revascularization, with balloon angioplasty (PTA) with or without stenting (S) being the most widely accepted endovascular option. The outcome of PTA ± S in the SFA has been studied previously in retrospective series, which suggested primary patency rates of 60% at 36-month follow-up.[6] There is evidence that shorter lesions (TransAtlantic Inter-Society Consensus [TASC] II A and B) do well with PTA/S, while longer lesions (TASC II C and D) have significantly lower patency rates.[6-8] The latest TASC II recommendations include an endovascular approach for shorter lesions and a bypass for longer lesions.[5] However, given patients' demand for minimally invasive procedures, the current practice has focused on an endovascular-first approach for most patients, reserving open bypass for patients who failed that option. Our study seeks to evaluate if this practice is changing the pattern of patency for both treatment options.

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METHODS

Subjects. We reviewed the electronic medical records of all patients who presented to the Johns Hopkins Bayview Medical Center with intermittent claudication, rest pain, tissue loss, or gangrene of the lower extremities between September 1, 2005 and June 30, 2012. The Institutional Review Board under the Johns Hopkins Vascular Registry approved data collection. Patients were identified using the International Classification of Diseases, Ninth Revision codes appropriate to diagnosis of peripheral arterial disease (PAD) with all the possible presenting symptoms (440.20, 440.21, 440.22, 440.23, and 440.24). All symptomatic patients underwent noninvasive arterial Doppler studies. Only patients who had an abnormal arterial Doppler study (defined as ankle brachial index [ABI] < 0.9 or toe brachial index <0.65 confirming arterial insufficiency) were selected for this study. All patients with noncritical limb ischemia were advised to follow a structured exercise program with follow-up in 3-6 months or earlier if they experienced worsening of symptoms. Cilostazol was often prescribed for the patients to improve walking distance. Aggressive management of patients' risk factors was implemented including smoking cessation, antiplatelet therapy, and aggressive hypertension, hypercholesterolemia, and diabetes control. Only patients who failed conservative medical management with no improvement or worsening of claudication symptoms preventing them from performing their daily activities or patients presenting with critical limb ischemia underwent diagnostic angiography. Of the entire group, we included patients who received femoral-popliteal bypass (bypass group) or angioplasty and stenting of the femoral and/or above the knee popliteal artery (stent group).

Data. Patient age, sex, smoking status, and comorbidities (diabetes, hypertension, coronary artery disease [CAD], hyperlipidemia, cerebrovascular disease, and chronic obstructive pulmonary disease) were recorded. Patient symptoms and clinical findings were identified. Indications for the procedure were recorded, and ABI for each patient was recorded. Lesion characteristics indentified on diagnostic angiography by the operating surgeon were reported in accordance with the TASC II classification standard.[5] A second independent reviewer on the research team verified all lesions' TASC II classification.

Treatment strategy. Most patients with extensive lesions (TASC II C and D) were offered bypass surgery. Few patients with extensive lesions but who were considered high risk for surgery were treated with PTA/S. Most patients with less extensive lesions (TASC II A and B) were treated with PTA/S during the initial angiography. Few patients who could not be treated with the PTA/S because of difficulty crossing the lesions were offered bypass surgery.

PTA/S techniques. All PTA/S were performed either in the interventional radiology or hybrid endovascular operating suite, both with fixed imaging capabilities. Arterial access was usually obtained from contralateral groin to evaluate the inflow vessels, followed by an up an over access of the affected limb and placement of a 40-cm 6F Balkin sheath (Cook Peripheral Inc, Bloomington, Ind). Few patients with difficult tortuous aortoiliac anatomy underwent antegrade access on the affected limb. Patients with normal renal function received Omnipaque contrast (General Electric Health Care Inc, Princeton NJ) using power injector. Patients with creatinine 1.5-2.0 received preoperative hydration with standard bicarbonate infusion, whereas Visipaque (General Electric Health Care Inc) was used for contrast. Patients with creatinine greater than 2.0 received angiography with carbon dioxide and minimal amount of Visipaque (<30 cc) through selective catheterization. Accurate measurement of lesions length and vessel diameter were obtained utilizing marker catheter or tape and calibration technique. Distal run off vessels were documented prior to crossing the lesions. All patients were systemically anticoagulated with heparin (60-80 IU/kg). Lesions were crossed with glide wire and angled tapered glide catheter (Terumo Medical Corporation, Somerset, NJ). Subintimal technique was used for most complete occlusive lesions. A re-entry device, the Outback (Cordis, Bridgewater, NJ) was needed in very few patients. Angiographic confirmation of re-entry into the true lumen was documented. PTA was performed on all patients utilizing 4-6 mm diameter and appropriate length balloons.

We attempted crossing all lesions including TASC II C and D lesions. Patients with lesions extending proximal to 2 cm below the origin of the SFA or distal to the level of the medial epicondyle into the popliteal artery were offered surgery. All patients received a self-expanding noncovered nitinol stent from various manufacturers (Absolute; Abbott Vascular, Santa Clara Calif, Smart; Cordis, Zilver; Cook Peripheral Inc, Luminex and Life; Bard Inc, Murray Hill NJ). A single stent was preferred to cover the entire lesion plus at least 0.5 cm proximal and 0.5 cm distal to the target lesion. Stent diameter was determined to oversize the original vessel diameter by approximately 1 mm. When more than one stent was used, we overlapped the stent by at least 1 cm. All stents were ballooned to ensure proper opposition to the vessel wall. The final angiogram documented normal flow in the stented lesions and runoff vessels. Postoperatively, all patients received loading dose of 300 mg of clopidogrel (Bristol-Myers Squibb, New York, NY) followed by 75 mg daily for at least 4-6 weeks and 81 mg of aspirin daily indefinitely. Statin-based drugs were used in patients with hyperlipidemia.

Bypass techniques. Patients received preoperative beta blockade and statin medications and continued with aspirin therapy. All patients underwent preoperative venous mapping in our vascular laboratory. Veins with diameter equal to or greater than 3.5 mm were considered adequate conduits for bypass. Techniques for surgical bypass included using autogenous veins, reversed or in situ. Arm veins were used in few patients when the greater saphenous veins were previously used. Spliced autogenous vein graft was used if a single vein segment was inadequate in length. Synthetic polytetrafluoroethylene (PTFE) grafts were rarely used only if autogenous veins were unavailable.

Follow-up. All patients were followed at the vascular clinic postoperatively. Patients were scheduled and encouraged to follow-up at 1, 3, 6, and 12 months during the first postoperative year and yearly thereafter. Noninvasive testing including duplex ultrasound and ABIs were performed at follow-up visits. Patients were contacted by phone and mail if lost to follow-up. Social security death index was used to determine mortality for loss of contact patients. Patient risk modifications were emphasized during the follow-up visits including smoking cessation and nicotine replacement therapy, antiplatelet and tight hypercholesterolemia control with target low-density lipoprotein of <75 mg/dL and hyperglycemia control with target A1c of <53 mmol/mol (7.0%). This was carefully communicated with the primary care giver and/or the primary cardiologist.

Outcome assessment. Patency was determined by vascular duplex ultrasound study and ABI in conjunction with pulse examination. Duplex criteria for significant (>50%) stenosis was defined as loss of reverse flow; marked spectral broadening; blunted waveform distal to stenosis as well as increased peak systolic velocity >300 cm/s in-stent or bypass graft, or a ratio of >3.0 of the stenosed segment highest velocity to the immediate proximal normal segment velocity or end diastolic velocity <45 cm/s in the bypass graft.[9] An angiogram was performed in patients with significant restenosis. If the stenosis was confirmed to be greater than 50% on angiography, reintervention was performed. Primary patency was calculated from the time of the initial revascularization procedure until an intervention was performed for restenosis or until there was complete occlusion/thrombosis of the bypass or stent. Patients who had an intervention for restenosis, not occlusion, contributed to primary-assisted patency. Primary-assisted patency was calculated from the time of the initial revascularization procedure through reintervention procedure until there was complete occlusion on duplex or angiogram.

Methods of reintervention. Vein grafts with stenotic lesions shorter than 3 cm were treated with angioplasty. For lesions longer than 3 cm or if restenosis occurred after two angioplasty procedures, veins grafts were treated with open patch angioplasty or interposition vein grafts for long lesions. Treatment of in-stent restenosis and intimal hyperplasia was accomplished with angioplasty alone. Restenting was reserved for fractured stents only.

Statistical analysis. Descriptive statistics were calculated using two-sided *t*-tests, χ^2 (Pearson and Fisher exact) tests to evaluate differences in patient demographics and comorbidities between treatment groups. The χ^2 tests (Pearson and Fisher exact) were also used to evaluate differences in TASC II classification. Using the Kaplan-Meier survival estimates, the overall patency (primary and primary-assisted) was compared between the two treatment groups, with the bypass group as the reference. Patient data were censored if patients were lost to follow-up and were considered a failure at the time there was a terminating event (patency failure, mortality, and limb loss). Log-rank tests calculated differences in patency rates (primary and primary-assisted) between the two treatment groups. Kaplan-Meier estimates were also used to compare primary patency and primary-assisted patency within TASC II subgroups. Using the Cox-proportional hazard regression model with robust variance,[10] we performed univariate analysis to estimate the crude hazard ratio (HR) of failure associated with procedure type with the bypass group as the reference. A univariate analysis of HR of failure was also performed for other patient risk factors. Subsequently, adjusted Cox proportional HRs were calculated comparing stent placement to bypass controlling for TASC II lesion types, age, sex, smoking history, hypertension, CAD, cerebrovascular accident, and chronic obstructive pulmonary disease. To estimate differences between the two treatment groups, the Fischer exact test was used to estimate *P* values for categorical variables, while the two-sided *t*-test was used for continuous variables.

Partial likelihood ratio test were used to fit the best model for our multivariable Cox regression analysis. All statistical analysis was done using Stata MP v. 11.0 (StataCorp, College Station, Tex). Statistical significance was defined as $P < .05$.

RESULTS

There were 1237 patients who presented with presumptive diagnosis of PAD in outpatient and inpatient settings at Johns Hopkins Bayview Medical Center between September 1, 2005 and June 30, 2012. Only 104 patients (8%) fit the inclusion criteria of the study, among which 61 received PTA/S, whereas 43 received femoral-popliteal bypass (37 with veins and six with PTFE grafts). All synthetic grafts were used for above-the-knee bypass. There were 13 below-the-knee bypasses all with veins.

The follow-up period had a maximum of 81 months with a median follow-up of 24 months and a mean follow-up of 26 months. We have excluded one patient who had no follow-up at all after the initial procedure.

Approximately, one-half of the patients (n = 53; 51%) presented with critical limb ischemia, of which 23 patients (22%) had rest pain and 30 patients (29%) had tissue loss and gangrene. Intermittent claudication was the presenting symptom in 51 patients (49%). The distribution of intermittent claudication vs critical limb ischemia was similar in both treatment groups. The baseline patient characteristics are illustrated in Table I. Patients' mean age was similar in both treatment groups: 65.8 (95% confidence interval [CI], 62.8-68.7) in the bypass group and 65.6 (95% CI, 62.7-68.6; $P = .96$) in the stent group. There were 61 males (58.7%) and 43 females (41.4%). The stent group had similar sex distribution (54% males vs 46% females), whereas the bypass group had more males (65% males vs 35% female). However, the distribution of sex between the two groups was not significantly different ($P = .26$).

The prevalence of cardiovascular risk factors (hypertension, CAD, cerebrovascular accident, smoking, and dyslipidemia) was similar across groups, except for diabetes, which was marginally higher in the stent group (64% vs 46%; $P = .07$).

The majority of patients had TASC B lesions (n = 43), followed by TASC D (n = 29), TASC A (n = 23), and TASC C (n = 9). Overall, 77% of patients with TASC A

Table I. Patient demographics and risk factors

	Bypass group (n = 43)	*Stent graft group (n = 61)*	P *value*
Mean age, years	65.8 (62.8-68.7)	65.6 (62.7-68.6)	.96[a]
Sex			.26[b]
Male (n = 61; 58.7%)	28 (65%)	33 (54%)	
Female (n = 43; 41.4%)	15 (35%)	28 (46%)	
Smoking history	28 (65%)	43 (70%)	.69[b]
Diabetes	20 (46%)	39 (64%)	.07[b]
CAD	27 (63%)	34 (56%)	.47[b]
Hypertension	33 (77%)	49 (82%)	.65[b]
Hyperlipidemia	32 (74%)	50 (82%)	.35[b]
CVA	4 (9.3%)	3 (4.9%)	.38[b]
COPD	8 (19%)	17 (28%)	.27[b]
TASC II category			<.01[b]
A	2 (8.7%)	21 (91.3%)	
B	13 (30.2%)	30 (69.8%)	
C	4 (44.4%)	5 (55.6%)	
D	24 (82.8%)	5 (17.2%)	
TASC II category combined			<.01[b]
A and B	15 (22.7%)	51 (77.3%)	
C and D	28 (73.7%)	10 (26.3%)	
Preop mean ABI	0.47	0.59	.078
Postop mean ABI	0.91	0.91	.94
Mean ABI improvement (SD)	0.44 (0.05) (n = 30)	0.32 (0.04) (n = 49)	.068

ABI, Ankle brachial index; *CAD,* coronary artery disease; *CVA,* cerebrovascular accident; *COPD,* chronic obstructive pulmonary disease; *SD,* standard deviation; *TASC,* TransAtlantic Inter-Society Consensus.
[a]Two-tailed *t*-test with pooled variance.
[b]Two-tailed Fisher exact test.

and B lesions received stents, whereas 73% of patients with TASC C and D lesions received bypass ($P < .01$). ABI values were falsely elevated or missing in 13 patients in the bypass group and 12 patients in the stent group. Although the stent group had higher preoperative mean ABI than the bypass group (0.59 vs 0.47; $P = .078$), the postoperative mean ABI was the same in both groups (0.91; $P = .94$). There was significant and similar improvement in mean ABI for both stent and bypass groups postoperatively (0.32 vs 0.44; $P = .068$) Table I.

The cumulative proportion of primary patency at 24 months, using the Kaplan-Meier survival estimates, was 67% in the stent group (95% CI, 0.52-0.78) vs 49% in the bypass group (95% CI, 0.32-0.64; $P = .05$) (Fig 1). There were 23 reintervention procedures in 16 patients (37%) in the bypass group (20 with PTA, two with interposition vein graft, and one with vein patch angioplasty) compared with 19 intervention procedures in 14 patients (22.9%) in the stent group (15 with PTA and four with PTA/S). The rate of reintervention within the 2-year period was higher in the bypass group compared with the stent group (53.5% vs 31%; $P = .02$). The cumulative proportion of patients with primary-assisted patency was similar for patients receiving stent 73% (95% CI, 0.56-0.85) vs bypass 81% (95% CI, 0.67-0.90; $P = .36$) (Fig 2).

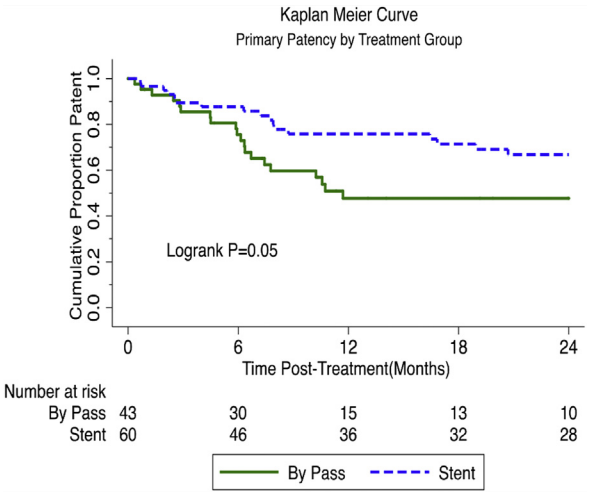

Fig 1. Primary patency in the stent group compared with the bypass group.

Survival analysis showed no significant difference in the maintenance of patency across TASC II groups comparing stent vs bypass. However, when TASC II groups A and B were combined and compared with the combined groups of TASC II C and D, patency was greater among the first group (log-rank $P = .01$) (Fig 3).

Cox proportional hazard models demonstrated a trend toward reduced risk of primary patency failure among patients receiving stents compared with those undergoing bypass procedures (HR, 0.53; 95% CI, 0.28-1.01; $P = .06$). However, this trend was lost after adjusting for patients' characteristics and lesions' TASC II types (HR, 0.73; 95% CI, 0.28-1.90; $P = .52$) (Table II). TASC C and D lesions combined demonstrated a 2.8-fold increase in hazard of patency failure compared with TASC A and B lesions combined (HR, 2.81; 95% CI, 1.13-6.69; $P = .02$) (Table II). Females had an almost twofold increase in hazard of patency failure (HR, 1.99; 95% CI, 1.10-3.90; $P = .04$) (Table II). There was no significant difference in the mortality rate (mortality incidence rate ratio, 1.54; 95% CI, 0.08-90.8; $P = .77$). The limb salvage rate was similar in both groups (90.7% in the bypass group vs 93.5% in the stent group; $P = .55$).

DISCUSSION

The 2-year primary-assisted patency rate of femoral-popliteal above the knee bypass with autogenous graft is 81%.[1] However, these figures represent 15-year-old data prior to the popularity of the endovascular approach. We believe that the majority of patients receiving bypass in today's practice have much more advanced disease. In our group 74% of patients with TASC II C and D lesions received a bypass. It is not surprising that these bypasses would have lower patency than the historically reported data.

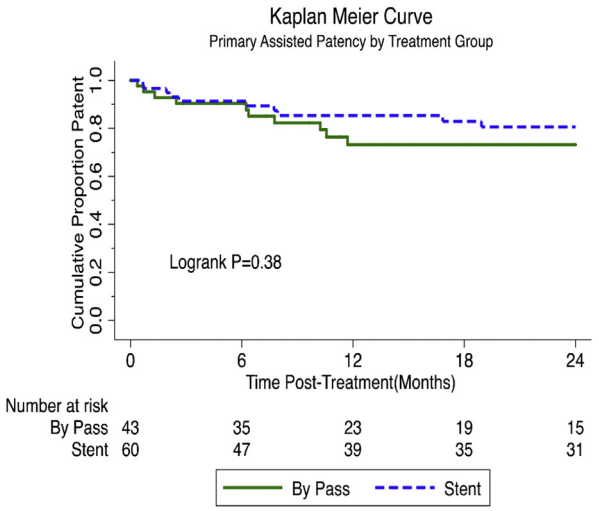

Fig 2. Primary-assisted patency in the stent group compared with the bypass group.

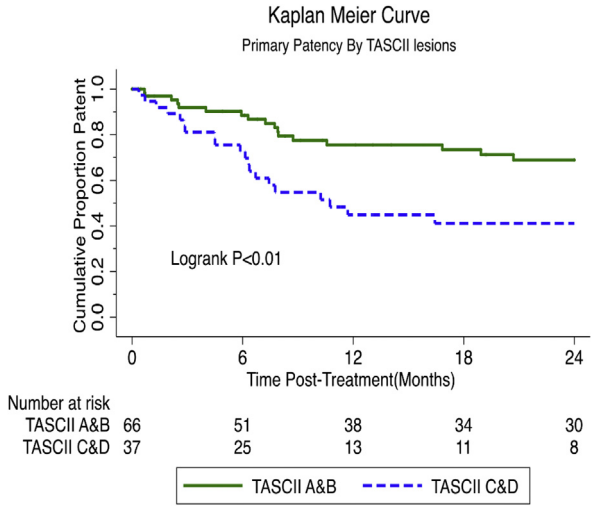

Fig 3. Primary patency for all patients (stent vs bypass), adjusted for TransAtlantic Inter-Society Consensus (*TASC*) II lesion type.

Stents used today are of a self-expanding, open-cell design made of nitinol (a mixture of nickel and titanium). They are designed to accommodate the severe stresses encountered in the SFA, including angulations, rotation, and longitudinal compression.[11] Improved durability of stenting in the femoral artery has been reported with the use of nitinol stents.[12-16] In three prospective randomized trials, Randomized Study Comparing the Edwards Self-Expanding Lifestent vs Angioplasty Alone in Lesions Involving the Superficial Femoral Artery and/or Proximal Popliteal Artery (RESILIENT),[17] The Femoral Artery Stenting Trial (FAST),[18] and the Vienna study,[19] adding a self-expanding nitinol stent significantly improved the 6- to 12-month patency rate of PTA alone in TASC A lesions (Table III). The first generation of drug eluting stents using polymer and Limus drug coating did not show a significant improvement in primary patency compared with bare metal stent.[16] More recently, in a randomized clinical trial, nonpolymer Paclitaxel coated Zilver PTX stents (Cook Medical Inc, Bloomington, Ind) are showing promising results with improved 2-year primary patency compared with bare metal stent (81% vs 63%, respectively; $P < .01$).[20] Surowiec et al performed a retrospective analysis comparing PTA ± S with bypass and reported a similar 2-year primary patency of the endovascular group compared with our study[6] (Table IV). The length of the lesion inversely related to the patency for the stent. TASC A lesions had similar patency to vein grafts, whereas TASC B lesions had similar patency to PTFE grafts.[6] The comparison group in this study was from patients who underwent a bypass 8-13 years prior to the popularity of the endovascular-first approach. Dearing et al reported 80% 1-year primary patency for primary stenting of TASC II A and B lesions compared with 50% in TASC II C and D lesions.[7] The 2-year primary-assisted patency in this study was comparable to our results (75% vs 81%). The prior two studies both recommended an endovascular option for TASC II A and B lesions and bypass for TASC II C and D lesions. This is consistent with the most recent TASC II recommendations.[5] However, the treatment choice remains largely biased by the treating physician's comfort and experience and not necessarily based on the durability of treatment method. McQuade et al conducted a prospective randomized study comparing femoral-popliteal bypass with synthetic grafts to endovascular stenting with expanded PTFE/nitinol self-expanding stent graft (Viabahn; W. L. Gore, Flagstaff, Ariz).[21] This study showed no significant difference in primary and secondary patency at 1-, 2-, 3-, and 4-year follow-up between the two groups. The 1-year primary patency of the stent graft was similar to the prior two studies and to our own nitinol stent group. However, the 2-year secondary patency was slightly lower than our primary-assisted patency for the stent and bypass groups (Table IV). Most of our patients in the bypass group received an autogenous graft (88%), and all the patients in the endovascular group received a self-expanding noncovered nitinol stent. Table IV summarizes the primary and primary-assisted patency of PTA/S among the last three studies in comparison with our study. Our limb salvage rate was similar in both groups.

The Basil trial compared angioplasty first with bypass first for patients presenting with severe limb ischemia because of infrainguinal disease. The long-term follow-up showed no significant difference in amputation free survival and overall survival up to 2-year follow-up. However, patients who survived beyond the 2 years did better in the surgical group. The immediate failure rate of angioplasty was as high as 25%, and the re-intervention rate was significantly higher in this group compared with the bypass group.[22] There are several factors that might have contributed to the different results in our study. First, the Basil trial has included patients with both above and below knee disease. The durability of above knee

Table II. Analysis of factors associated with loss of patency

	Unadjusted		*Adjusted*[a]	
Characteristics	*HR (95% CI)*	P *value*	*HR (95% CI)*	P *value*
Treatment				
Bypass	Reference		Reference	
Stent	0.53 (0.28-1.01)	.06	0.73 (0.28-1.90)	.52
TASC lesion combined				
TASC A and B	Reference			
TASC C and D	2.42 (1.26-4.65)	<.01	2.81 (1.13-6.69)	.02
TASC lesion				
A	Reference			
B	0.41 (0.16-1.0)	.06	0.34 (0.13-0.87)	.02
C	0.84 (0.19-3.68)	.82	0.82 (0.12-5.55)	.83
D	1.67 (0.78-3.57)	.19	1.79 (0.59-5.44)	.30
Female	1.43 (0.75-2.73)	.28	1.99 (1.10-3.90)	.04
Smoking History	1.14 (0.57-2.31)	.71	1.20 (0.64-2.25)	.56
Diabetes	1.56 (0.78-3.09)	.20	2.13 (0.81-5.66)	.13
Hyperlipidemia	0.79 (0.36-1.75)	.57	0.91 (0.33-0.45)	.85
Hypertension	0.50 (0.25-1.00)	.05	0.33 (0.16-0.65)	<.01
CVA	2.12 (0.84-5.34)	.11	2.31 (0.88-6.06)	.08
COPD	0.73 (0.31-1.70)	.47	0.94 (0.37-2.41)	.89

CI, Confidence interval; *CVA,* cerebrovascular accident; *COPD,* chronic obstructive pulmonary disease; *HR,* hazard ratio; *TASC,* TransAtlantic Inter-Society Consensus.
[a]Adjusted for lesion length and patient characteristics.

Table III. Summary of the results of three prospective randomized trials comparing the patency of PTA alone vs PTA with nitinol stent

Trials	*Patients*	*Stent type*	*Mean length*	*PTA patency*	*PTA/S patency*
RESILIENT	206	Life Stent	6.5 cm	45% (12-month)	87% (12-month)
FAST	244	Luminex	4.5 cm	61.7% (6-month)	74.5% (6-month)
Vienna	104	Various nitinol stents	5.9 cm	37% (12-month)	63% (12-month)

FAST, Femoral Artery Stenting Trial; *PTA,* percutaneous transluminal angioplasty; *RESILIENT,* Randomized Study Comparing the Edwards Self-Expanding Lifestent vs Angioplasty Alone in Lesions Involving the Superficial Femoral Artery and/or Proximal Popliteal Artery; *S,* stenting.

Table IV. Comparison of the results of our study to the most recent published studies evaluating the primary and primary-assisted patency for PTA/S of the SFA

Study	*Year*	*No.*	*Follow-up*	*Primary patency*	*Assisted patency*	*TASC*
Surowiec[6]	2005	380	24-month	66%	-	A > B > C > D A = vein, B = PTFE
McQuade[20]	2010	100	24-month	63%	74%	No difference
Dearing[7]	2011	239	24-month	55%	75%	A and B > C and D
Malas	2012	104	24-month	67%	81%	A and B > C and D

PTA, Percutaneous transluminal angioplasty; *PTFE,* polytetrafluoroethylene; *S,* stenting; *SFA,* superficial femoral artery; *TASC,* TransAtlantic Inter-Society Consensus.

SFA endovascular interventions is clearly better than popliteal and tibial interventions. Second, all of our patients received a stent in addition to angioplasty, which is different than the Basil trial where patients in the endovascular group underwent angioplasty only.

Our study has several limitations. The sample size is small (104 patients), which resulted in reducing the ability of the model to show a statistically significant association of several of the covariates with the outcome variable. Another important limitation in this study is the strong correlation between lesion characteristics and the procedure chosen. Our study is confounded by indication and selection bias because most long lesions were selected for bypass, whereas most of the short lesions were selected for stenting.

CONCLUSIONS

Open bypass remains the gold standard for revascularization of the lower extremity. This treatment method has been extensively evaluated in several prospective well-designed studies, which have shown it to be effective in

long-term limb salvage and improving patients' quality of life. Nevertheless, over the last decade there has been a significant shift in the treatment paradigm with an endovascular first approach on all patients evolving in many centers. Therefore, patients undergoing a bypass graft today have much more advanced disease. This is the first study that demonstrates a higher rate of reintervention for femoral-popliteal bypass compared with angioplasty and stenting. It also clearly demonstrates that the two patient populations are not equivalent, with much more extensive disease treated in the bypass cohort. This study illustrates the strong necessity for a well-designed prospective randomized trial to compare the two treatment modalities, which we are currently conducting in our institution. This will help eliminate the selection bias in retrospective study and provide level-one evidence on the effectiveness of both procedures.

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AUTHOR CONTRIBUTIONS

Conception and design: MM, BP
Analysis and interpretation: MM, NE, BB, ES
Data collection: UQ
Writing the article: MM, JF, BP, TR
Critical revision of the article: MM, JF, BP
Final approval of the article: MM, JF, BP
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Overall responsibility: MM, UQ

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